REMARKS

Claims 1-11, 13, 18-23, 26-29, 31-41, 45, 47-50, 53, 57-69, and 71-88 remain in the application. Claim 1 is amended by incorporating therein the limitation of "non-invasive" of claim 12, which is accordingly canceled. Claim 1 is also amended to emphasize distinctions over cited art; see, e.g., paragraph 0051 (acoustic matching layer 9) and paragraph 0056 (non-invasive coupling). Claims 1, 23, 57, 59, 71, 77, 85, and 86 are amended to overcome various objections/rejections as discussed below. Claims 12, 14-17, 24, 25, 30, 42-44, 46, 51, 52, 54-56, and 70 are canceled.

The drawings are objected to under 37 CFR 1.83(a). The Examiner contends that the means for exciting the acoustic emitter, the means for acoustically coupling the acoustic energy into the deposits, the means for operating the emitter, the inflatable balloon used to administer a drug, as well as the imaging device that is integrated or co-mounted with the acoustic emitter must be shown or the feature(s) canceled from the claim(s).

The "means for exciting the acoustic emitter" is deleted from the claims, thereby obviating that portion of the objection.

The "means for acoustically coupling the acoustic energy into the deposits" is re-worded to recite "an acoustic matching layer for non-contact acoustic coupling of the acoustic beam directly into the deposits". The acoustic matching layer is denoted as element 9.

The "means for operating the emitter" is replaced with "the emitter configured to ...", thereby obviating that portion of the objection.

The "inflatable balloon used to administer a drug" is deleted from the claims, thereby obviating that portion of the objection.

The "imaging device that is integrated or co-mounted with the acoustic emitter: is deleted from the claims, thereby obviating that portion of the objection.

Reconsideration of the objection to the drawings under 37 CFR 1.83(a) is respectfully requested.

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because the reference characters "7" and "8" have both been used to designate the acoustic emitter.

In response thereto, Applicants submit that rather than revising the drawings, the text needs to be modified as appropriate. As stated in paragraph 0051, item 7 is variously an ultrasound probe or acoustic device. The device comprises an acoustic emitter 8 and an acoustic matching layer 9, also called a transducer. The specification has been amended at paragraphs 0053, 0068, 0074, and 0077 to be consistent with paragraph 0051.

Reconsideration of the objection to the drawings as failing to comply with 37 CFR 1.84(p)(4) is respectfully requested.

The Examiner objects to the specification as failing to provide for proper antecedent basis for the claimed subject matter, citing 37 CFR 1.75(d)(1) and MPEP 608.01(o). Specifically, the Examiner notes that there is no antecedent basis for the 'means for exciting said acoustic emitter'; the 'means for acoustically coupling said acoustic energy into said deposits'; or the 'means for operating said emitter' that is claimed in Claim 1.

The "means" phrases have been re-drafted (or omitted), as the case may be, and antecedent basis is provided for the elements of the apparatus recited in amended claim 1.

Reconsideration of the objection to the specification is respectfully requested.

Claims 1-88 are rejected under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Claims 12, 14-17, 24, 25, 30, 42-44, 46, 51, 52, 54-56, and 70 are canceled.

Regarding claim 1, the Examiner objects to "means for exciting said acoustic emitter"; the "means for acoustically coupling said acoustic energy into said deposits"; and the "means for operating said emitter".

Applicants have dealt with this aspect above.

Further regarding claim 1, the Examiner objects to "optionally" as being a relative term that renders the claim indefinite.

The Examiner has not cited any basis, statutory or otherwise, for holding that "optionally" renders the claim indefinite. Indeed, "optionally" is much like the alternative "or", which has been held to be definite (either a or b is claimed, and there is definite-

ness thereby). Likewise, either the drug is present or it is absent. There is no indefiniteness in this, and the Examiner has not shown that there is any indefiniteness.

In the experience of the undersigned representative, not having "optionally" in a claim such as Applicants have done often results in an objection by an examiner when the optional element is omitted from the independent claim and introduced in a dependent claim. The objection is to broadening the claim. The only other approach is to provide a separate independent claim, which will have the effect of approximately doubling the number of claims, since two parallel sets of claims would have to be provided.

The Examiner is respectfully requested to cite authority for her position that "optionally" renders the claim indefinite or withdraw the rejection.

Regarding claims 2-84, the objection to these claims for the same reasons as the objections to claim 1 should now be overcome. With regard to claims 85-88, it should be noted that claims 85 and 86 are both independent claims (and claims 87-88 depend from claim 86). These claims do not depend from claim 1, and the rejection of these claims by the Examiner as being dependent on claim 1 and thus indefinite for the same reason as claim 1 is inapposite.

Specific claims are additionally objected to for other reasons. These are now dealt with.

Regarding claim 23, the phrase "in any manner" is considered to render the claim indefinite.

The phrase has been deleted.

Further regarding claim 23, the mention of "a drug" renders the claim indefinite, as it is unclear whether the drug being referred to is that of Claim 1 or another drug.

Claim 23 is amended to refer to the drug recited in claim 1.

Regarding claim 57, the phrase "in any manner" is considered to be indefinite.

The phrase has been deleted.

Regarding claim 70, the Examiner objects to the range "milliwatts/cm^2 to kilowatts/cm^2 as being indefinite for not providing a number.

Claim 70 is canceled, and dependent claim 71 is amended to depend from Claim 1.

Regarding claim 77, the Examiner objects to "optionally" as being a relative term that renders the claim indefinite.

In the spirit of advancing the prosecution, the term "optionally" is deleted from Claim 77.

Regarding claim 85, the Examiner objects to "optionally" as being a relative term that renders the claim indefinite. For the record, claim 85 does not depend from claim 1, as asserted by the Examiner, but rather is an independent claim.

For the reasons advanced above with regard to the recitation of "optionally" in claim 1, the recitation of "optionally" in claim 85 is considered to be appropriate.

Regarding claim 86, the phrase "in any manner" is considered to render the claim indefinite.

The phrase has been deleted in both locations.

Regarding claims 86-88, the objection to these claims for the same reasons as the objections to claim 85 should now be overcome.

Reconsideration of the rejection of claims 1-11, 13, 18-23, 26-29, 31-41, 45, 47-50, 53, 57-69, and 71-88, as amended, under 35 USC 112, second paragraph, is respectfully requested.

Claims 1-84 are rejected under 35 USC 101 as being directed to non-statutory subject matter. Claims 12, 14-17, 24, 25, 30, 42-44, 46, 51, 52, 54-56, and 70 are canceled.

The Examiner considers that the phrase "means for acoustically coupling said acoustic energy into said deposits", based on paragraph 0057, implies claiming a human being (or portion thereof).

Applicants have responded to the indefinite rejection above. It is noted that Applicants are claiming an apparatus for removing, break-down, or erosion of undesirable deposits. Perforce, such deposits have to be mentioned in the claims, but there is no intent to claim them as part of the apparatus. If the Examiner has language that would be more suitable than that employed by Applicants, Applicants would be happy to entertain such suggested language. In this connection, two of the issued patents applied against the claims by the Examiner contain similar language: see, e.g., U.S. Patent 6,361,554 to Brisken ("A method for inhibiting hyperplasia at a site in a patient's vasculature where a prosthesis has been implanted") and U.S. Patent 4,870,953 to

DonMicheal et al ("An ultrasonic apparatus for the treatment of a patient having blood vessels obstructed by deposits of atherosclerotic plaque or blood clots").

Reconsideration of the rejection of claims 1-11, 13, 18-23, 26-29, 31-41, 45, 47-50, 53, 57-69, and 71-88, as amended, under 35 USC 101 as being directed to non-statutory subject matter is respectfully requested.

The instant Office Action begins with an argument that various features of Applicants' claims may be ignored as statements of intended use. This is entirely incorrect.

MPEP § 2114 clearly and unequivocally states that "features of an apparatus may be recited either structurally or functionally." (MPEP § 2114). "There is nothing inherently wrong with defining some part of an invention in functional terms. Functional language does not, in and of itself, render a claim improper. *In re Swinehart*, 439 F.2d 210, 169 USPQ 226 (CCPA 1971)." (MPEP § 2173.05(g).) To the contrary, "[a] functional limitation ***must*** be evaluated and considered, just like any other limitation of the claim, for what it fairly conveys to a person of ordinary skill in the pertinent art in the context in which it is used." (MPEP § 2173.05(g)) (emphasis added).

Moreover, those experienced in drafting and prosecuting patents will appreciate that a functional recitation will frequently imply and require a specific corresponding structure. However, the functional recitation provides a more definitive description of the invention than would trying to specify the underlying structure. Consequently, functional limitations cannot be ignored or swept aside by the Examiner's fiat. To the contrary, again, "[a] functional limitation ***must*** be evaluated and considered, just like any other limitation of the claim, for what it fairly conveys to a person of ordinary skill in the pertinent art in the context in which it is used." (MPEP § 2173.05(g)) (emphasis added). Thus, language directed to the cleaning of moving parts, such as valves, leaflets, occluders, and articulating implanted devices, etc., which the cited references fail to teach, as discussed below, is considered to be appropriate in light of the foregoing, and should be considered by the Examiner.

Claims 1-28, 33-49, 51, 53, 55-59, 62-67, 69, 74, and 79-85 are rejected under 35 USC 102(b) as being anticipated by U.S. Patent 5,725,494 to Brisken (Brisken '494). Claims 12, 14-17, 24, 25, 42-44, 46, 51, and 56 are canceled.

Brisken '494, listed in paragraph 0014 and in an Information Disclosure Statement filed with the application, discloses apparatus and methods for ultrasonically enhanced intraluminal therapy. An ultrasonic catheter comprises a catheter body having a resonantly vibrating assembly at its distal end. The resonantly vibrating assembly comprises a tail mass, an interface member, and a spring element which connects the tail mass to the interface member. An interface surface is formed on the interface member and is forwardly disposed at the distal end of the catheter. A longitudinally oscillating driver is disposed between the tail mass and the interface member, and the catheter can be connected to a suitable power supply to induce oscillations in the driver. The driver is typically a piezoelectric device, such as a tubular piezoelectric transducer or a piezoelectric stack. The characteristics of the interface member, spring element, and longitudinally oscillating driver are selected so that the interface member may be resonantly vibrated at an ultrasonic frequency. The catheter is useful for treating luminal conditions, such as vascular clot and plaque. Optionally, a therapeutic agent may be delivered through the catheter simultaneously with the application of ultrasonic energy.

Claim 1, as amended, recites:

> 1. Apparatus for the non-contact or damage-free, *non-invasive* removal, breakdown or erosion of undesirable existing deposits situated: on or in (i) an implanted artificial device, (ii) an implanted bioprosthetic device or (iii) a natural body part having at least one moving or movable part or portionthe existing deposits interfering or potentially interfering with at least one of (a) the designed proper function or maintenance of said implanted device or body part or (b) a natural circulatory system process necessary for normal healthy living, said apparatus comprising:
>
> an acoustic emitter capable of emitting a beam of acoustic energy;
>
> *an acoustic matching layer for non-contact, non-invasive acoustic coupling of said acoustic beam into said deposits via impingement of the beam upon or into the deposits*;
>
> said emitter configured to at least partially remove, breakdown or otherwise erode said existing deposits with said beam; and

> optionally, an administered drug to aid said removal or erosion process, to prevent or slow further such deposits, or to treat a side-effect of treatment with said acoustic emitter. (Emphasis added.)

Brisken '494 fails to disclose an acoustic matching layer for non-contact, non-invasive acoustic coupling of the acoustic beam into the deposits via impingement of the beam upon or into the deposits.

Also, there is no teaching or suggestion in Brisken '494 as to cleaning moving parts, such as valves (leaflets or occluders 3A-3B) – only the interior walls of lumens. There is therefore no teaching as to avoiding damage to any moving or movable (articulating) parts or portions. Applicants' recite that the apparatus is for the removal of existing deposits situated: on or in (i) an implanted artificial device, (ii) an implanted bioprosthetic device or (iii) a natural body part having at least one moving or movable part or portion.

Further, the device is invasive, as it passes through lumens. Applicants have limited their claims to the non-invasive aspect of their invention, as taught, e.g., in paragraph 0055.

Finally, the cleaning of artificial implants is not mentioned by Brisken '494.

Reconsideration of the rejection of claims 1-11, 13, 18-23, 26-28, 33-41, 45, 47-49, 53, 57-59, 62-67, 69, 74, and 79-85, as amended, under 35 USC 102(b) as being anticipated by U.S. Patent 5,725,494 to Brisken is respectfully requested.

Claims 1 and 73 are rejected under 35 USC 102(e) as being anticipated by U.S. Patent Application Publication 2003/0009153 to Brisken (Brisken '153).

Brisken '153 discloses the ultrasonic enhancement of drug injection. A method of enhancing cellular absorption of a substance delivered into a target region of a patient's body comprises (a) delivering the substance to the target region, and (b) directing vibrational energy to the target region, wherein the vibrational energy is of a type and amount sufficient to enhance absorption into cells of the target region.

Claim 1 is discussed above.

Brisken '153 fails to disclose an acoustic matching layer for non-contact, non-invasive acoustic coupling of the acoustic beam into the deposits via impingement of the beam upon or into the deposits.

Further, this patent teaches ultrasonic enhancement of drug injection via enhanced cellular penetration. It is the opposite of cleaning - one is depositing a foreign material in the body permanently and not removing any material at all. There is therefore no teaching as to foulants, directing drugs to foulants or directing ultrasound to foulants. In particular, there is no disclosure or suggestion of the non-invasive removal of deposits from moving body parts, such as valves.

Reconsideration of the rejection of claims 1 and 73, as amended, under 35 USC 102(e) as being anticipated by U.S. Patent Application Publication 2003/0009153 to Brisken is respectfully requested.

Claims 1 and 75 are rejected under 35 USC 102(e) as being anticipated by U.S. Patent Application Publication 2004/0024347 to Wilson et al.

Wilson et al disclose a catheter with multiple ultrasound radiating members. The catheter delivers ultrasonic energy and therapeutic compounds to a treatment site within a patient's vasculature.

Claim 1 is discussed above.

Wilson fails to disclose an acoustic matching layer for non-contact, non-invasive acoustic coupling of the acoustic beam into the deposits via impingement of the beam upon or into the deposits.

The Wilson device enhances drug delivery into lumens, which is an invasive procedure, and its uniqueness is that it does so along extended lengths of the lumen. However, Wilson et al teach nothing about articulating parts, acoustic assessment of foulants or cleaning of moving parts non-invasively.

Reconsideration of the rejection of claims 1 and 75, as amended, under 35 USC 102(e) as being anticipated by U.S. Patent Application Publication 2004/0024347 to Wilson is respectfully requested.

Claims 86-87 are rejected under 35 USC 102(b) as being anticipated by U.S. Patent Application Publication 2001/0039383 to Mohler.

Mohler discloses passive, non-invasive systemic and pulmonary blood pressure measurement.

Claim 86, as amended, reads:

> 86. A method of assessing the state of fouling by undesirable deposits of an implant or of a natural valve in a living body, the implant

or valve having at least one moving or movable part, said method comprising:

obtaining an acoustic signature of the operation of said implant or valve or valve-model at least under unfouled conditions inside or outside a living body;

obtaining, using passive reception or pulse-echo active probing, an acoustic signature of said implant or valve thought to possibly have fouling thereon or therein;

the possibly-fouled signature containing at least one of: (1) naturally generated acoustic features known to be caused by fouling, and (2) artificially excited features known to be excited upon the presence of fouling;

comparing the fingerprints looking for fouling features that have newly been incorporated into the signature; and

concluding that newly added features which match known fouling features indicate fouling.

Mohler's device deduces pulmonary blood pressure from valve closing noise. It is deducing blood pressure and not any state of fouling. It does not teach acoustic attributes of fouling nor does it have sufficiently broad bandwidth to do so in that the suggested frequency range is 200-2000 hertz. There is no discussion of fouling or cleaning. No active pinging is taught or suggested.

Reconsideration of the rejection of claims 86-87, as amended, under 35 USC 102(b) as being anticipated by U.S. Patent Application Publication 2001/0039383 to Mohler is respectfully requested.

Claims 29-30, 52, 68, and 70-72 are rejected under 35 USC 103(a) as being patentable over Brisken '494, *supra*, in view of U.S. Patent 6,361,554 to Brisken (Brisken '554). Claims 30, 52, and 70 are canceled.

Brisken '494 is discussed above, and the comments regarding this reference obtain here as well. Brisken '554, like Brisken '494, is listed in paragraph 0014 and in the IDS Brisken '554 discloses methods and apparatus for the subcutaneous delivery of acoustic vibrations to an implanted structure. As an example, the implanted structure is a stent and the vibrational energy is intented to inhibit hyperplasia in a blood vessel in which the stent is implanted.

Brisken '554 teaches resonating artificial implants at rather low frequencies of 50-100 KHz whereby the implant then reradiates the energy into adjacent irritated tissue (irritated by the implant's placement). First, it should be noted that one is

taught to preferably do this treatment shortly after implant at a time when there is not any stent overgrowth; thus, this approach is ***preventative***. Second, it should be noted that no teaching has energy directly attacingk stent foulants, not even reradiated energy. The objective of the invention is tissue overgrowth ***prevention***, not removal. The entire implant is exposed to energy, so addressing the moving part of an implant is not taught - stents have no moving parts. So the Brisken '554 invention does not involve articulating parts, does not clean foulants from anything - articulating or not - and does not even expose foulants to the direct attack of ultrasound.

The rejected claims all depend, directly or indirectly, from claim 1, which, as amended, emphasizes the non-invasive cleaning of existing deposits from movable parts (such as valves). The references, in combination, clearly fail to disclose or suggest such apparatus. Thus, the rejected claims must be deemed patentable over the combination of references.

Reconsideration of the rejection of claims 29, 68, 71, and 72, as amended, under 35 USC 103(a) as being patentable over Brisken '494 in view of Brisken '554 is respectfully requested.

Claims 31-32, 50, and 76-78 are rejected under 35 USC 103(a) as being patentable over Brisken '494, *supra*, in view of U.S. Patent 4,870,953 to DonMicheal.

Brisken '494 is discussed above, and the comments regarding this reference obtain here as well. DonMicheal discloses an intravascular ultrasonic catheter/probe and method for treating intravascular blockage. Again, as with Brisken '494, this is an invasive procedure for cleaning the plaque from the walls of vasculature, not for cleaning moving parts, such as valves.

DonMicheal discloses the use of an ultrasonically excited wire for cleaning lumens. Because it is a wire, it cannot perform acoustic assessment of foulants. It cleans by chipping or beating upon the foulant, actions which would clearly damage an artificial heart valve, for example. Because of the direct-contact cleaning, it cannot be considered a directed beam capable of standoff cleaning. It would probably damage or tear a lumen valve.

The rejected claims all depend, directly or indirectly, from claim 1, which, as amended, emphasizes the non-invasive cleaning of existing deposits from movable parts (such as valves). The references, in combination, clearly fail to disclose or

suggest such apparatus. Thus, the rejected claims must be deemed patentable over the combination of references.

Reconsideration of the rejection of claims 31-32, 50, and 76-78, as amended, under 35 USC 103(a) as being patentable over Brisken '494 in view of DonMicheal is respectfully requested.

Claims 60-61 are rejected under 35 USC 103(a) as being patentable over Brisken '494, *supra*, in view of U.S. Patent 5,853,005 to Scanlon.

Brisken '494 is discussed above, and the comments regarding this reference obtain here as well. Scanlon discloses an acoustic monitoring system, comprising a transducer in communication with fluid in a pad held in close contact against a sound or movement source to monitor acoustic signals transferred into the liquid.

Scanlon is an entirely passive acoustic listening device aimed primarily at globally detectable noises such as snoring, breathing, tossing and turning, and crying. These phenomena occur in the 1-160 hertz regime, which is actually audible sound and not ultrasound. The preferred detector is a very large sensor pad whose reception is omni-directional and not directed as for an acoustic beam. There is no mention of foulants or foulant-related noises. There is no mention of actively pinging.

The rejected claims both depend from claim 1, which, as amended, emphasizes the non-invasive cleaning of existing deposits from movable parts (such as valves). The references, in combination, clearly fail to disclose or suggest such apparatus. Thus, the rejected claims must be deemed patentable over the combination of references.

Reconsideration of the rejection of claims 60-61 under 35 USC 103(a) as being patentable over Brisken '494 in view of Scanlon is respectfully requested.

The Examiner cites the following references as being pertinent to Applicants' disclosure: U.S. Patent 7,335,169 (Thompson), U.S. Patent 6,635,017 (Moehring), U.S. Patent 3,433,226 (Boyd), and U.S. Patent Application 2003/0171803 (Shimon). Applicants have reviewed these references and consider that they neither disclose nor suggest Applicants' claimed invention, whether taken alone, in any reasonable combination with each other, or in any reasonable combination with the above-discussed references.

The foregoing amendments and arguments are submitted to place the application in condition for allowance. The Examiner is respectfully requested to take such action. If the Examiner has any questions, she is invited to contact the undersigned at the below-listed telephone number.

Respectfully submitted,

CAROL A. TOSAYA ET AL

December 23, 2008

David W. Collins
Attorney for Applicants
Registration No. 26,857

512 East Whitehouse Canyon Road
Suite 100
Green Valley, AZ 85614

Telephone calls may be made to:
(520) 399-3203